

WHAT IS CLAIMED IS:

1. An active agent delivery system having a target diffusivity, the system comprising an active agent and a miscible polymer blend; wherein:

5 the active agent is hydrophobic and has a molecular weight of no greater than about 1200 g/mol; and

the miscible polymer blend comprises at least two polymers, each with at least one solubility parameter, wherein:

10 the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about $10 \text{ J}^{1/2}/\text{cm}^{3/2}$, and the difference between at least one solubility parameter of each of at least two polymers is no greater than about $5 \text{ J}^{1/2}/\text{cm}^{3/2}$;

15 at least one polymer has an active agent diffusivity higher than the target diffusivity and at least one polymer has an active agent diffusivity lower than the target diffusivity;

the molar average solubility parameter of the blend is no greater than $25 \text{ J}^{1/2}/\text{cm}^{3/2}$; and

20 the swellability of the blend is no greater than 10% by volume.

2. The system of claim 1 wherein:

25 the miscible polymer blend does not include a blend of a hydrophobic cellulose derivative and a polyurethane or a polyvinyl pyrrolidone; and/or

the miscible polymer blend does not include a blend of a polyalkyl methacrylate and a polyethylene-co-vinyl acetate.

30 3. The system of claim 1 wherein the difference between at least one Tg of at least two of the polymers corresponds to a range of diffusivities that includes the target diffusivity.

4. The system of claim 1 wherein the active agent is incorporated within the miscible polymer blend.
5. The system of claim 1 wherein the miscible polymer blend initially provides a barrier for permeation of the active agent.
6. The system of claim 6 wherein the active agent is incorporated within an inner matrix.
7. The system of claim 1 wherein the miscible polymer blend includes at least one hydrophobic polymer.
8. The system of claim 1 wherein the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about $5 \text{ J}^{1/2}/\text{cm}^{3/2}$.
9. The system of claim 1 wherein the difference between at least one solubility parameter of each of at least two of the polymers is no greater than about $3 \text{ J}^{1/2}/\text{cm}^{3/2}$.
10. An active agent delivery system having a target diffusivity, the system comprising an active agent and a miscible polymer blend; wherein:
- the active agent is hydrophilic and has a molecular weight of no greater than about 1200 g/mol; and
- the miscible polymer blend comprises at least two polymers, wherein:
- the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about $10 \text{ J}^{1/2}/\text{cm}^{3/2}$, and the difference between at least one solubility parameter of each of at least two polymers is no greater than about $5 \text{ J}^{1/2}/\text{cm}^{3/2}$;

at least one polymer has an active agent diffusivity higher than the target diffusivity and at least one polymer has an active agent diffusivity lower than the target diffusivity;

5 the molar average solubility parameter of the blend is greater than $25 \text{ J}^{1/2}/\text{cm}^{3/2}$; and

the swellability of the blend is no greater than 10% by volume.

11. The system of claim 10 wherein the miscible polymer blend does
10 not include both a hydrophobic cellulose derivative and a polyvinyl pyrrolidone.

12. The system of claim 10 wherein the difference between at least one Tg of at least two of the polymers corresponds to a range of
15 diffusivities that includes the target diffusivity.

13. The system of claim 10 wherein the active agent is incorporated within the miscible polymer blend.

20 14. The system of claim 10 wherein the miscible polymer blend initially provides a barrier for permeation of the active agent.

15. The system of claim 14 wherein the active agent is incorporated within an inner matrix.

25 16. The system of claim 10 wherein the miscible polymer blend includes at least one hydrophilic polymer.

17. The system of claim 10 wherein the difference between the
30 solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about $5 \text{ J}^{1/2}/\text{cm}^{3/2}$.

18. The system of claim 10 wherein the difference between at least one solubility parameter of each of at least two of the polymers is no greater than about $3 \text{ J}^{1/2}/\text{cm}^{3/2}$.
- 5 19. The system of claim 10 wherein the miscible polymer blend comprises one or more polymers selected from the group consisting of polyacrylonitriles, cyanoacrylates, methacrylonitriles, hydrophilic cellulose, and combinations thereof.
- 10 20. An active agent delivery system having a target diffusivity, the system comprising an active agent and a miscible polymer blend; wherein:
- the active agent is hydrophobic and has a molecular weight of greater than about 1200 g/mol; and
- 15 the miscible polymer blend comprises at least two polymers, wherein:
- the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about $10 \text{ J}^{1/2}/\text{cm}^{3/2}$, and the
- 20 difference between at least one solubility parameter of each of at least two polymers is no greater than about $5 \text{ J}^{1/2}/\text{cm}^{3/2}$;
- at least one polymer has an active agent diffusivity higher than the target diffusivity and at least one polymer has an active agent diffusivity lower than the target diffusivity;
- 25 the molar average solubility parameter of the blend is no greater than $25 \text{ J}^{1/2}/\text{cm}^{3/2}$; and
- the swellability of the blend is greater than 10% by volume.
21. The system of claim 20 wherein:
- 30 the miscible polymer blend does not include a blend of a hydrophobic cellulose derivative and a polyurethane or a polyvinyl pyrrolidone; and/or

the miscible polymer blend does not include a blend of a polyalkyl methacrylate and a polyethylene-co-vinyl acetate.

22. The system of claim 20 wherein the difference between the
5 swellabilities of at least two of the polymers corresponds to a range of diffusivities that includes the target diffusivity.

23. The system of claim 20 wherein the active agent is incorporated within the miscible polymer blend.

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24. The system of claim 20 wherein the miscible polymer blend initially provides a barrier for permeation of the active agent.

25. The system of claim 24 wherein the active agent is incorporated
15 within an inner matrix.

26. The system of claim 20 wherein the miscible polymer blend includes at least one hydrophobic polymer.

20 27. The system of claim 26 wherein the miscible polymer blend includes a second polymer that is hydrophilic.

28. The system of claim 27 wherein the hydrophilic polymer is a hydrophilic polyurethane.

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29. The system of claim 20 wherein the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about 5 $J^{1/2}/cm^{3/2}$.

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30. The system of claim 20 wherein the difference between at least one solubility parameter of each of at least two of the polymers is no greater than about 3 $J^{1/2}/cm^{3/2}$.

31. The system of claim 20 wherein the active agent is not heparin.

32. An active agent delivery system having a target diffusivity, the system comprising an active agent and a miscible polymer blend;

5 wherein:

the active agent is hydrophilic and has a molecular weight of greater than about 1200 g/mol; and

the miscible polymer blend comprises at least two polymers, wherein:

10 the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about $10 \text{ J}^{1/2}/\text{cm}^{3/2}$, and the difference between at least one solubility parameter of each of at least two polymers is no greater than about $5 \text{ J}^{1/2}/\text{cm}^{3/2}$;

15 at least one polymer has an active agent diffusivity higher than the target diffusivity and at least one polymer has an active agent diffusivity lower than the target diffusivity;

the molar average solubility parameter of the blend is greater than $25 \text{ J}^{1/2}/\text{cm}^{3/2}$; and

20 the swellability of the blend is greater than 10% by volume.

33. The system of claim 32 wherein the miscible polymer blend does not include both a hydrophobic cellulose derivative and a polyvinyl pyrrolidone.

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34. The system of claim 32 wherein the difference between the swellabilities of at least two of the polymers corresponds to a range of diffusivities that includes the target diffusivity.

30 35. The system of claim 32 wherein the active agent is incorporated within the miscible polymer blend.

36. The system of claim 32 wherein the miscible polymer blend initially provides a barrier for permeation of the active agent.

37. The system of claim 36 wherein the active agent is incorporated within an inner matrix.

38. The system of claim 32 wherein the miscible polymer blend includes at least one hydrophilic polymer.

39. The system of claim 38 wherein one polymer is a hydrophilic polyurethane.

40. The system of claim 38 wherein the miscible polymer blend includes a second polymer that is hydrophobic.

41. The system of claim 32 wherein the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about 5 $J^{1/2}/cm^{3/2}$.

42. The system of claim 32 wherein the difference between at least one solubility parameter of each of at least two of the polymers is no greater than about 3 $J^{1/2}/cm^{3/2}$.

43. The system of claim 32 wherein the active agent is not heparin.

44. A medical device comprising the active agent delivery system of claim 1.

45. The medical device of claim 44 selected from the group consisting of a stent, stent graft, anastomotic connector, lead, needle, guide wire, catheter, sensor, surgical instrument, angioplasty balloon, wound drain, shunt, tubing, urethral insert, pellet, implant, blood

oxygenator, pump, vascular graft, valve, pacemaker, orthopedic device, replacement device for nucleus pulposus, and intraocular lense.

5 46. A medical device comprising the active agent delivery system of claim 10.

47. The medical device of claim 46 selected from the group consisting of a stent, stent graft, anastomotic connector, lead, needle, guide wire, catheter, sensor, surgical instrument, angioplasty balloon, 10 wound drain, shunt, tubing, urethral insert, pellet, implant, blood oxygenator, pump, vascular graft, valve, pacemaker, orthopedic device, replacement device for nucleus pulposus, and intraocular lense.

15 48. A medical device comprising the active agent delivery system of claim 20.

49. The medical device of claim 48 selected from the group consisting of a stent, stent graft, anastomotic connector, lead, needle, guide wire, catheter, sensor, surgical instrument, angioplasty balloon, 20 wound drain, shunt, tubing, urethral insert, pellet, implant, blood oxygenator, pump, vascular graft, valve, pacemaker, orthopedic device, replacement device for nucleus pulposus, and intraocular lense.

25 50. A medical device comprising the active agent delivery system of claim 32.

51. The medical device of claim 50 selected from the group consisting of a stent, stent graft, anastomotic connector, lead, needle, guide wire, catheter, sensor, surgical instrument, angioplasty balloon, 30 wound drain, shunt, tubing, urethral insert, pellet, implant, blood oxygenator, pump, vascular graft, valve, pacemaker, orthopedic device, replacement device for nucleus pulposus, and intraocular lense.

52. A stent comprising the active agent delivery system of claim 1.
53. A stent comprising the active agent delivery system of claim 10.
- 5 54. A stent comprising the active agent delivery system of claim 20.
55. A stent comprising the active agent delivery system of claim 32.
56. A method of designing an active agent delivery system for
10 delivering an active agent over a preselected dissolution time (t) through
a preselected critical dimension (x) of a miscible polymer blend, the
method comprising:
 providing an active agent having a molecular weight no greater
 than about 1200 g/mol;
15 selecting at least two polymers, wherein:
 the difference between the solubility parameter of the
 active agent and at least one solubility parameter of each of the
 polymers is no greater than about $10 \text{ J}^{1/2}/\text{cm}^{3/2}$, and the difference
 between at least one solubility parameter of each of the at least
20 two polymers is no greater than about $5 \text{ J}^{1/2}/\text{cm}^{3/2}$; and
 the difference between at least one T_g of each of the at
 least two polymers is sufficient to include the target diffusivity;
 combining the at least two polymers to form a miscible polymer
 blend;
25 and
 combining the miscible polymer blend with the active agent to
 form an active agent delivery system having the preselected dissolution
 time through a preselected critical dimension of the miscible polymer
 blend.
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57. The method of claim 56 wherein the active agent is incorporated
within the miscible polymer blend.

58. The method of claim 56 wherein miscible polymer blend initially provides a barrier for permeation of the active agent.

59. The method of claim 56 wherein the active agent is incorporated within an inner matrix.

60. The method of claim 56 wherein the active agent is hydrophobic.

61. The method of claim 56 wherein the active agent is hydrophilic.

62. The method of claim 48 wherein:

the miscible polymer blend does not include a blend of a hydrophobic cellulose derivative and a polyurethane or a polyvinyl pyrrolidone; and/or

the miscible polymer blend does not include a blend of a polyalkyl methacrylate and a polyethylene-co-vinyl acetate.

63. A method of designing an active agent delivery system for delivering an active agent over a preselected dissolution time (t) through a preselected critical dimension (x) of a miscible polymer blend, the method comprising:

providing an active agent having a molecular weight greater than about 1200 g/mol;

selecting at least two polymers, wherein:

the difference between the solubility parameter of the active agent and at least one solubility parameter of each of the polymers is no greater than about $10 \text{ J}^{1/2}/\text{cm}^{3/2}$, and the difference between at least one solubility parameter of each of the at least two polymers is no greater than about $5 \text{ J}^{1/2}/\text{cm}^{3/2}$; and

the difference between the swellabilities of the at least two polymers is sufficient to include the target diffusivity;

combining the at least two polymers to form a miscible polymer blend;

and
combining the miscible polymer blend with the active agent to
form an active agent delivery system having the preselected dissolution
time through a preselected critical dimension of the miscible polymer
blend.

64. The method of claim 63 wherein the active agent is incorporated
within the miscible polymer blend.

65. The method of claim 63 wherein miscible polymer blend initially
provides a barrier for permeation of the active agent.

66. The method of claim 63 wherein the active agent is incorporated
within an inner matrix.

67. The method of claim 63 wherein the active agent is hydrophobic.

68. The method of claim 63 wherein the active agent is hydrophilic.

69. The method of claim 63 wherein the active agent is not heparin.

70. The method of claim 63 wherein:

the miscible polymer blend does not include a blend of a
hydrophobic cellulose derivative and a polyurethane or a polyvinyl
pyrrolidone; and/or

the miscible polymer blend does not include a blend of a polyalkyl
methacrylate and a polyethylene-co-vinyl acetate.

71. A method for delivering an active agent to a subject, the method
comprising:

providing the active agent delivery system of claim 1; and
contacting the active agent delivery system with a bodily fluid,
organ, or tissue of a subject.

72. A method for delivering an active agent to a subject, the method comprising:

providing the active agent delivery system of claim 10; and
contacting the active agent delivery system with a bodily fluid,
5 organ, or tissue of a subject.

73. A method for delivering an active agent to a subject, the method comprising:

providing the active agent delivery system of claim 20; and
10 contacting the active agent delivery system with a bodily fluid,
organ, or tissue of a subject.

74. A method for delivering an active agent to a subject, the method comprising:

15 providing the active agent delivery system of claim 32; and
contacting the active agent delivery system with a bodily fluid,
organ, or tissue of a subject.